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November 1, 2006

Gary L. Kepplinger
General Counsel
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Kepplinger,

Thank you for providing me a copy of your October 18 letter to Secretary Leavitt regarding applicability of Section 317P of the Public Health Service Act to federally funded abstinence education programs.

As the author of this law, I have been concerned about the lack of enforcement of many of its provisions for some time. The law was written, in fact, because federal health agencies, condom manufactures and advocacy groups were failing to provide medically accurate information about the lack of effectiveness of condoms in preventing human papillomavirus (HPV) infection. Clearly, the information provided by any federally funded health program should be expected to be medically accurate.

If GAO does undertake an investigation of those receiving federal funds to determine compliance with this law, I would strongly encourage that such a review not be limited to abstinence programs but rather examine the full scope of federal programs and agencies that provide educational and other services related to sexually transmitted diseases.

Additionally, I am requesting that GAO investigate the failure of the Food and Drug Administration (FDA) to comply with the provision of the same law that requires the agency to "reexamine existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV." It has been six years since this law was signed and FDA has yet to issue guidance to ensure condom labels meet this criteria. As you noted in your letter, "Section 317P of the Public Health Service Act addresses human papillomavirus specifically." Yet, condom labels do not currently mention the lack of effectiveness of condoms in protecting against HPV infection, which has been conclusively documented over the past decade.

In February 1999 in a letter to the U.S. House Commerce Committee, Dr. Richard D. Klausner, then-Director of the National Cancer Institute, stated "Condoms are ineffective against HPV because the virus is prevalent not only in the mucosal tissue (genitalia) but also on dry skin of the surrounding abdomen and groin, and it can migrate

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from those areas into the vagina and the cervix. Additional research efforts by NCI on the effectiveness of condoms in preventing HPV transmission are not warranted."

In 2001, mere months after the law was signed, the National Institute of Allergy and Infectious Diseases issued a consensus report regarding condom effectiveness prepared with the input of other federal health agencies that found condoms reduced risk of HIV transmission and gonorrhea (for men only). "The Panel agreed that the published epidemiologic data were insufficient to draw meaningful conclusions about the effectiveness of the latex male condom to reduce the risk of transmission of genital ulcer diseases (genital herpes, syphilis and chancroid). … For HPV, the Panel concluded that there was no epidemiologic evidence that condom use reduced the risk of HPV infection." These findings contradicted the more conclusive claims provided for decades. It is fair to say, based upon the available scientific data, any claims that exaggerate condom effectiveness beyond the NIAID findings are not medically accurate, as required by law.

More recently, in January 2004 the Centers for Disease Control and Prevention (CDC) issued a report that concluded "The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection."

These findings should be included in all federally funded programs "that that are specifically designed to address STDs" and condom labels, as required by law. Since you have already reviewed a component of the applicability of this law to recipients of federal funding, I would appreciate if GAO could also investigate the compliance of the same law by the FDA, a government agency, specifically mentioned in the law.

As the author of Section 317P of the Public Health Service Act, I am disappointed that GAO did not consult with me when making the analysis of the law's intent. It seems reasonable that GAO, Congress and the public would benefit in the future if GAO analysis of Congressional intent was based upon discussions with the authors rather than guess work. Could you please provide a listing of any individuals or entities and their affiliations, including members of Congress or Congressional staff, that GAO met with when completing this review?

Thank you again and I would appreciate a timely response to this request. December 21 of this year marks the six year anniversary of the signing of this law and I am hopeful that a thorough GAO review of FDA actions may assist the agency come into compliance with the law.

Sincerely,

Tom A. Coburn, M.D.
U.S. Senator